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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/549,355	07/31/2006	Colin G. Caro	DEHN 2 00009	6723

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EXAMINER	
TANNER, JOCELIN C	
ART UNIT	PAPER NUMBER
3731	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/549,355	CARO ET AL.	
	Examiner	Art Unit	
	JOCELIN C. TANNER	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 August 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-6,9,10,12,13 and 15-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-6,9,10,12,13 and 15-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *14 September 2005* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is in response to the Amendment filed 21 August 2009. Claims 1, 3-6, 9, 10, 12, 13 and 15-28 are currently pending. The Examiner acknowledges new claims 24-28.

Drawings

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "stent having a helical center line that varies" must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner,

the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 24-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Regarding claim 24, in line 9, the recitation "a gentle swirl at an upstream end of the stent" is unclear as to what type of swirl is encompassed by the limitation of a "gentle swirl".

5. Claim 24 recites the limitation "the swirl effect" in line 10. There is insufficient antecedent basis for this limitation in the claim.

6. Regarding claim 24, in line 9, the recitation "helical center line varies" is vague since it is unclear which aspect, axes, direction or dimension of the helical center line is being referenced to change or alter.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 12, 13, 15-19, 21 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Houston et al. (US PGPub No. 2002/0179166A1) in view of Evans et al. (US Patent No. 5,709,713).

9. Regarding claim **12**, Houston et al. discloses a conduit that may be a mesh stent (11) [0025] that appears to be expandable since it is disclosed as being collapsible [0021], however, is not expressly disclosed as being expandable, the stent having an expanded configuration that is substantially free of ribs and having a helical center line and a helix angle of 8° that is within the claimed range of less than or equal to 65° ([0010], [0022], [0050], [0051], Fig. 5). Houston et al. fails to disclose an amplitude having a value less than or equal to 0.7 of the internal diameter of the tubing and to expressly disclose a stent that is expandable from a collapsed configuration.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have provided tubing having a helical center line with a claimed value of an amplitude less than or equal to 0.7 of the internal diameter, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Evans et al. teaches a mesh stent having a radially compressed and expanded configuration (column 5, lines 53-55).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the mesh stent of Houston et al. with expansion and collapsing means, as taught by Evans et al., to release and remove the stent during and following the desired treatment.

10. Regarding claim **13**, Houston et al. discloses a helical centre line formed by internal ridging that has an amplitude and tubing with an internal diameter. Houston et al. fails to disclose the value of 0.05 calculated by dividing the amplitude of the helical centre line by the internal diameter of the tubing.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have provided tubing with the claimed values found by dividing the amplitude of the helical centre line by the internal diameter, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

11. Regarding claim **15**, Houston et al. discloses Houston et al. discloses a stent (300) having an expanded configuration with a helical center line and a helix angle of 8° that is within the claimed range of less than or equal to 15° ([0010]).

12. Regarding claim **16**, Houston et al. discloses a stent having a circular cross-section (Fig. 5).

13. Regarding claim **17**, Houston et al. discloses a helical center line of the stent extending over part of the overall length of the stent (Fig. 5).

14. Regarding claim **18**, Houston et al. discloses a helical center line of the stent extending over substantially the entire length of the stent (Fig. 5).

15. Regarding claim **19**, Houston et al. discloses a helical center line following a substantially helical path about a curved axis (Fig. 5).

16. Regarding claim **21**, Houston et al. discloses a helical centre line formed by internal ridging that has an amplitude and tubing with an internal diameter. Houston fails to disclose the value of 0.1 calculated by dividing the amplitude of the helical centre line by the internal diameter of the tubing.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have provided tubing with the claimed values found by dividing the amplitude of the helical centre line by the internal diameter, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

17. Regarding claim **23**, Houston et al. discloses a stent having a helical portion that has the same number of turns in the expanded and collapsed conditions (Fig. 5).

18. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Houston et al. (US PGPub No. 2002/0179166A1) in view of Evans et al. (US Patent No. 5,709,713), as applied to claim 12 above, and further in view of Igaki et al. (US Patent No. 5,733,327).

Regarding claim **20**, the combination of Houston et al. and Evans et al. discloses all of the limitations previously discussed except for a pharmaceutical coating.

Igaki et al teach coating a stent to provide locally limited and long-term dosage of drugs (column 2, line 51 and column 3, lines 19-22).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the stent of the combination of Houston

et al. and Evans et al., with the coating or drug induced fiber, as taught by Igaki et al., to provide locally limited and long-term dosage of drugs.

19. Claims 1, 3-6 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Houston et al. (US PGPub No. 2002/0179166A1) in view of Evans et al. (US Patent No. 5,709,713), as applied to claim 12 above, and further in view of Hogan (US Patent No. 6,569,191).

20. Regarding claim **1**, Houston et al. in view of Evans et al. discloses a stent (11) having a helix structure and formed of a synthetic material and having an outer wall that radially expands. The combination of Houston et al. and Evans et al. fails to disclose wall portions that have more of a resistance to extension than the helical portions.

Hogan teaches an expandable stent wherein rigid longitudinal strips (40) are attached to the helically wound threads that form the wall of the stent and exert an increased longitudinally constricting force (column **7**, lines 1-12, Fig. 4).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided longitudinal extension resistance to the stent of the combination of Houston et al. and Evans et al., as taught by Hogan, to increase radial expansion to obtain a desired final diameter.

21. Regarding claim **3**, Hogan teaches helical supplemental threads (30) of different material or thickness that increase the amount of stent forming material (column 6, lines 33-37, Fig. 2).

22. Regarding claim **4**, Houston et al. discloses a stent having curved or "bent" portions wherein the bent portions remain bent when expanded (Fig. 5).

23. Regarding claims **5 and 6**, Hogan teaches a self- expanding and balloon-expandable stent (column 8, lines 17-21).

24. Regarding claim **22**, Houston et al. discloses a stent (11) undergoing a turn of the helix wherein the stent has a helical configuration with at least one helical turn (Fig. 5).

25. Claims 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Houston et al. (US PGPub No. 2002/0179166A1) in view of Evans et al. (US Patent No. 5,709,713), as applied to claim 12 above, and further in view of Inderbitzen et al. (US Patent No. 5,484,411).

26. Regarding claim **9**, the combination of Houston et al. and Evans et al. discloses a balloon expandable stent (column 3, lines 2-6, Evans et al.). However, the combination of Houston et al. and Evans et al. fails to disclose a balloon having an expandable wall that resists extension more helical portions of the balloon.

Inderbitzen et al. teaches an expandable balloon used in angioplasty procedures including a longitudinally extending spiral wall (38) extending from the distal to proximal end of the balloon, formed integrally with the exterior surface of the balloon and radially restricting the expansion of the balloon along the longitudinally extending spiral path (column 3, lines 45-53, Fig. 2).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have constructed the balloon of the combination of Houston et al. and Evans et al., with a helical portion, as taught by Inderbitzen et al., to exhibit a low crossing profile and to avoid the need to rotate the balloon within a vessel to ensure dilation.

27. Regarding claim **10**, Inderbitzen et al. teaches a balloon having an exterior surface or expandable wall wherein the wall thickness is greater in sections include a spiral wall or "helical portion" (38) (Fig. 2).

28. **Claims 24-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Houston et al. (US PGPub No. 2002/0179166A1) in view of Evans et al. (US Patent No. 5,709,713) in view of Nunez et al. (6,596,023).**

29. Regarding claim **24**, Houston et al. discloses a conduit that may be a mesh stent (11) [0025] that appears to be expandable since it is disclosed as being collapsible [0021], however, is not expressly disclosed as being expandable, the stent having an expanded configuration that is substantially free of ribs and having a helical center line and a helix angle of 8° that is within the claimed range of less than or equal to 65° ([0010], [0022], [0050], [0051], Fig. 5). Houston et al. fails to disclose an amplitude having a value less than or equal to 0.7 of the internal diameter of the tubing and to expressly disclose a stent that is expandable from a collapsed configuration.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have provided tubing having a helical center line with a claimed value of an amplitude less than or equal to 0.7 of the internal diameter, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Evans et al. teaches a mesh stent having a radially compressed and expanded configuration (column 5, lines 53-55).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the mesh stent of Houston et al. with expansion and collapsing means, as taught by Evans et al., to release and remove the stent during and following the desired treatment.

However, the combination of Houston et al. and Evans et al. fails to disclose a conduit having a helical center line that varies along the length of the stent.

Nunez et al. teaches a mesh stent (column 16, lines 22-36) having a helical center line (Fig. 6) wherein the center line varies or changes form from one axis to another, the helical center line having the capability of introducing a gentle swirl to increase the swirling of the fluid.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the mesh stent of the combination of Houston et al. and Evans et al., with a varying helical center line, as taught by Nunez et al., to avoid the need to customize stents by using sutures (column 3, lines 49-55).

30. Regarding claims **26 and 27**, Nunez et al. teaches a stent having an angle that varies along the length of the stent wherein the angle is gradually altered with increasingly changing amplitude (Fig. 6).

31. Regarding claim **28**, Nunez et al. teaches a stent having a pitch and amplitude that change along the length of the stent (Fig. 7).

Response to Arguments

32. Applicant's arguments filed 21 August 2009 have been fully considered but they are not persuasive. In response to applicant's argument that claim 12 is directed

towards a stent for insertion into a fluid conduit, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. The scaffold of Houston is capable of being inserted into blood vessels to provide mechanical support or maintain flow guiding formation through a vessel. In response to applicant's argument that the stent of the instant application is permanently placed in a vessel, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the stent is permanently implanted) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). The Applicant contends that the combination of Houston et al. and Evans et al. fails to disclose the stent as being substantially free of ribs that would project into the flow lumen. However, there are no ribs or ridges within or outside of the helical shaped conduit (Fig. 5) as opposed to the ribs that extend into and out of the conduit of Fig. 6.

Conclusion

33. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOCELIN C. TANNER whose telephone number is (571)270-5202. The examiner can normally be reached on Monday through Thursday between 9am and 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jocelin C. Tanner/
11/30/2009
Examiner, Art Unit 3731

/Anhtuan T. Nguyen/
Supervisory Patent Examiner, Art Unit 3731
12/03/09